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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,678	03/19/2004	Saverio Carl Falco	BB1037USCNT	9737

23906 7590 09/28/2007  
E I DU PONT DE NEMOURS AND COMPANY  
LEGAL PATENT RECORDS CENTER  
BARLEY MILL PLAZA 25/1128  
4417 LANCASTER PIKE  
WILMINGTON, DE 19805

EXAMINER
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MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

NOTIFICATION DATE	DELIVERY MODE
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09/28/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-Legal.PRC@usa.dupont.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/804,678	<b>Applicant(s)</b> FALCO ET AL.	
	<b>Examiner</b> Elizabeth F. McElwain	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The amendment filed July 20, 2007 has been entered.

Claims 1-38 have been cancelled.

Claims 39, 44 and 49 are newly amended.

Claims 39-53 are pending and examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

1. Claims 39-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth in the last office action.

2. Applicants' arguments filed July 20, 2007 have been fully considered but they are not persuasive. Applicants submit as appendices to the response: a diagram of the first two steps of the alpha-aminoacidic acid pathway; sequence alignments of LKR domains; sequence alignments of SDH domains; and sequence alignments of LKR/SDH bifunctional proteins. Applicants argue that conserved regions are shown and that one skilled in the art could use these alignments to determine which amino acids could modify function, and that sequence similarity between the yeast and plant saccharopine dehydrogenase is shown in Figure 9 of the specification. Applicants also submitted Tang et al and Epelbaum et al taught LKR and SDH

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bifunctional proteins in papers published in 1997. The Examiner maintains that Applicant is relying on diagrams that are not part of the specification and on post-filing date publications (in view of priority claimed), which were not available at the time of the invention.

3. Applicants further state that Dr. Carl Falco's Declaration of August 24, 2000 was previously submitted and provides evidence that a 1268 bp gene fragment of SEQ ID NO: 122 was successfully used to increase lysine and was correlated with cosuppression of LKR/SDH. The Examiner maintains that a review of the papers filed in the present application did not identify the Falco Declaration of August 24, 2000. The filing date of said declaration in the present application is requested. Furthermore, it appears that the Falco Declaration only provides one example of a sequence that functions, as claimed, where one example of a sequence is not sufficient to support the claimed genus of any nucleic acid sequence which is useful in inhibition of endogenous LKR/SDH activity in a plant or plant cell. The specification does not provide information regarding what structural features would confer either type of enzyme activity, and furthermore what sequences would be sufficient for use in antisense inhibition or sense suppression of LKR/SDH.

4. Claims 39-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated in the last office action.

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5. Applicants' arguments filed July 20, 2007 have been fully considered but they are not persuasive. Applicants assert that the arguments set forth above pertain to the present rejection. However, the Examiner maintains that the Falco Declaration has not been provided, and that the specification does not teach sequences that function as claimed or provide guidance with regard to choosing sequences that would function in the claimed manner. Applicants further argue that increasing lysine levels in a plant by modifying lysine biosynthetic and catabolic pathways was known and would not require undue experimentation. The Examiner maintains that modifying plant biosynthetic pathways by transforming a plant with a nucleic acid is unpredictable and that applicant has not provided guidance with regard to identifying nucleic acid sequences that would function in this manner, and neither have any examples been provided. Therefore, for the reasons of record set forth in the last office action, it would require undue experimentation to make and/or use the claimed invention.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Elizabeth F. McElwain  
Primary Examiner  
Art Unit 1638

EFM